EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION
CIVIL ACTION NO. 2:12-md-02327

MDL No. 2327

Judge Joseph R. Goodwin
This Document Applies To All Actions

DEFENDANTS' RESPONSES TO PLAINTIFFS' FIRST REQUESTS FOR ADMISSION

Pursuant to Federal Rule of Civil Procedure 36, Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson, Inc. ("Johnson & Johnson") (collectively, "Defendants"),[1] hereby make the following objections and provide the following responses to Plaintiffs' First Requests for Admission ("Requests").

Pursuant to Federal Rule of Civil Procedure 26(e), Defendants reserve the right to supplement their responses to the Requests if Defendants learn of additional information.

REQUESTS TO ADMIT

REQUEST NO. 1: Admit that you never completed a controlled study involving live women with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 1. Defendants admit that they did not complete a randomized controlled trial with the actual TVT device prior

[1] Defendants note that apart from Defendants Ethicon and Johnson & Johnson, the other entities identified in Paragraph 1 of the "Definitions" section of Plaintiffs' First Requests for Admission to Defendants are not identified as Defendants in the First Amended Long Form Complaint and Amended Short Form Complaint. Pursuant to agreement of the parties, Ethicon, LLC will not be identified as a defendant in the Second Amended Long Form Complaint and thus, no response is required.

to marketing and selling the TVT in the United States, but Ethicon complied with FDA regulations and the 510(k) clearance process.

REQUEST NO. 2: Admit that you never completed a randomized controlled trial with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 2. Defendants admit that they did not complete a randomized controlled trial with the actual TVT device prior to marketing and selling the TVT in the United States, but Ethicon complied with FDA regulations and the 510(k) clearance process.

REQUEST NO. 3: Admit that the mesh used in the TVT is and has always been the Prolene* 6 mil that was first used in hernia mesh sold by defendants in approximately 1974, as illustrated in ETH.MESH.01816990, attached hereto.

RESPONSE:

Admit.

REQUEST NO. 4: Admit that the mesh used in the TVT is, and has always been, the mesh with the specifications identified in the document titled Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 4. Defendants admit that TVT has always been made in conformance with the applicable material specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT mesh is revision 10.

REQUEST NO. 5: Admit that the mesh used in the TVT is, and always has been, the same "Old Construction Prolene* Mesh" as defined in the Material Specifications for TVT Prolene*, ETH.MESH.06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 5. Defendants admit that TVT mesh is and always has been the "Old Construction PROLENE* Mesh" pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT mesh is revision 10.

REQUEST NO. 6: Admit that the mesh used in the TVT is, and has always been, manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 6. Defendants admit that TVT is and has always been manufactured using 6 mil clear and/or 6 mil dyed monofilament polypropylene pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT mesh is revision 10.

REQUEST NO. 7: Admit that the mesh used in the TVT weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 7. The current version of the process specification for manufacturing the TVT mesh does not utilize or define the measurement "grams per meters squared." Defendants admit, however, that 102 grams per meters squared falls within the specification of 3 ounces per squared yard plus or minus ½ ounce which equates to approximately 78 grams to approximately 109 grams per meters squared.

REQUEST NO. 8: Admit that the average pores in the TVT mesh marketed and sold in the U.S. are, and have always been, less than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants object to Request No. 8 because the phrases "average pores" and "less than 1 mm in all directions" are vague and ambiguous and because there is no medical device industry standard to measure or define "average pore[]" sizes. Subject to and without waiving this objection, Defendants deny Request No. 8, except as hereinafter expressly admitted. Defendants admit that Ethicon measures TVT mesh via courses and wales, an industry standard in textile construction.

REQUEST NO. 9: Admit that the specifications for the TVT mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants admit that the specifications for TVT mesh marketed and sold in the U.S. do not contain a requirement that "the pores of the mesh . . . be greater than 1 mm in diameter in all directions when sold."

REQUEST NO. 10: Admit that the TVT mesh marketed and sold in the United States is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 10 because "heavyweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "heavyweight mesh," and because the referenced article does not specifically define "heavyweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 10, except as hereinafter expressly admitted. Defendants admit that PROLENE* mesh used in TVT is heavier in weight than Vypro mesh.

REQUEST NO. 11: Admit that the TVT mesh is not "lightweight mesh" as defined by: Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 11 because "lightweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "lightweight mesh," and because the referenced article does not specifically define "lightweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 11, except as hereinafter expressly admitted. Defendants admit that the PROLENE* mesh used in TVT is heavier in weight than Vypro mesh.

REQUEST NO. 12: Admit that the TVT-O has always been manufactured and sold in the U.S. with "Old Construction Prolene* Mesh" as defined in the Material Specification for TVT Prolene, ETH.MESH.06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 12. Defendants admit that TVT-O is and always has been the "Old Construction PROLENE* Mesh" pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT-O mesh is revision 10.

REQUEST NO. 13: Admit that the mesh used in the TVT-O is and has always been, manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 13. Defendants admit that TVT-O is and always has been manufactured using 6 mil clear and/or 6 mil dyed monofilament polypropylene pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT-O mesh is revision 10.

REQUEST NO. 14: Admit that the mesh used in the TVT-O weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 14. Defendants admit that the current version of the process specification for manufacturing the TVT-O mesh does not utilize or define the measurement "grams per meters squared." Defendants further admit, however, that 102 grams per meters squared falls within the specification of 3 ounces per squared yard plus or minus ½ ounce which equates to approximately 78 grams to approximately 109 grams per meters squared.

REQUEST NO. 15: Admit that the pores in the TVT-O mesh marketed and sold in the U.S are, and have always been, less than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants object to Request No. 15 because the phrase "less than 1 mm in diameter in all directions" is vague and ambiguous and because there is no medical device industry standard to measure or define pore sizes. Subject to and without waiving this objection, Defendants deny Request No. 15, except as hereinafter expressly admitted. Defendants admit that Ethicon measures TVT-O mesh via courses and wales, an industry standard in textile construction.

REQUEST NO. 16: Admit that the specifications for the TVT-O mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants admit that the specifications for the TVT-O mesh marketed and sold in the U.S. do not contain a requirement that "the pores of the mesh . . . be greater than 1 mm in diameter in all directions when sold."

REQUEST NO. 17: Admit that the mesh used in the TVT-O marketed and sold in the U.S. is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 17 because "heavyweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "heavyweight mesh," and because the referenced article does not specifically define the term "heavyweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 17, except as hereinafter expressly admitted. Defendants admit that PROLENE* mesh used in TVT-O is heavier in weight than Vypro mesh.

REQUEST NO. 18: Admit that the mesh used in the TVT-O is not "lightweight mesh" as defined by: Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 18 because "lightweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "lightweight mesh," and because the referenced article does not specifically define the term "lightweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 18, except as hereinafter expressly admitted. Defendants admit that the PROLENE* mesh used in TVT-O is heavier in weight than Vypro mesh.

REQUEST NO. 19: Admit that, with the exception of the ETHISORB®/PDS film ends, the TVT-S uses the same "Old Construction Prolene* Mesh" as defined in the Material Specifications for TVT Prolene, ETH.MESH.06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 19. Defendants admit that TVT-SECUR mesh is and always has been the "Old Construction PROLENE* Mesh" pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT-SECUR mesh is revision 10.

REQUEST NO. 20: Admit that, with the exception of the ETHISORB/PDS film ends, the mesh used in the TVT-S is and has always been manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 20. Defendants admit that TVT-SECUR is and always has been manufactured using 6 mil clear and/or 6 mil dyed monofilament polypropylene pursuant to the applicable version of the material process specification. Further, ETH.MESH.06136033 is the Material Specification for TVT PROLENE* Mesh Roll Stock and is revision 8. The current version of the process specification for manufacturing the TVT-SECUR mesh is revision 10.

REQUEST NO. 21: Admit that, with the exception of the ETHISORB/PDS film ends, the Prolene* mesh used in the TVT-S weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene, ETH.MESH 06136033, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 21. Defendants admit that the latest version of the process specification for manufacturing the TVT-SECUR mesh does not utilize or define the measurement "grams per meters squared." Defendants further admit, however, that 102 grams per meters squared falls within the specification of 3 ounces per squared yard plus or minus ½ ounce which equates to approximately 78 grams to approximately 109 grams per meters squared.

REQUEST NO. 22: Admit that the pores in the TVT-S mesh marketed and sold in the U.S are, and have always been, less than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants object to Request No. 22 because the phrase "less than 1 mm in diameter in all directions" is vague and ambiguous and because there is no medical device industry standard to measure or define pore sizes. Subject to and without waiving this objection, Defendants deny Request No. 22, except as hereinafter expressly admitted. Defendants admit that Ethicon measures TVT-SECUR mesh via courses and wales, an industry standard in textile construction.

REQUEST NO. 23: Admit that the specifications for the TVT-S mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

RESPONSE:

Defendants admit that the specifications for the TVT-SECUR mesh marketed and sold in the U.S. do not contain a requirement that "the pores of the mesh . . . be greater than 1 mm in diameter in all directions when sold."

REQUEST NO. 24: Admit that the TVT-S mesh marketed and sold in the United States is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 24 because "heavyweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "heavyweight mesh," and because the referenced article does not specifically define the term "heavyweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 24, except as hereinafter expressly admitted. Defendants admit that the PROLENE* mesh used in TVT-SECUR is heavier in weight than Vypro mesh.

REQUEST NO. 25: Admit that the TVT-S mesh is not "lightweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 25 because "lightweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to

measure or define "lightweight mesh," and because the referenced article does not specifically define the term "lightweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 25, except as hereinafter expressly admitted. Defendants admit that the PROLENE* mesh used in TVT-SECUR is heavier in weight than Vypro mesh.

REQUEST NO. 26: Admit that the mesh used in the TVT, TVT-O, and TVT-S devices is identical, with the exception of the ETHISORB®/PDS film ends on the TVT-S device.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 26. Defendants admit that, in general, TVT, TVT-O, and TVT-SECUR devices have the same type of PROLENE* mesh, but the mesh used in TVT-SECUR is a different length than the mesh used in TVT and TVT-O.

REQUEST NO. 27: Admit that the mesh used in the TVT device is identical to that used in the TVT-O device.

RESPONSE:

Admit.

REQUEST NO. 28: Admit that the intravaginal slingplasy ("IVS") device used in the Medscand Scandinavian Multicenter Study, the study report signed by Margareta Eriksson on October 17, 1997 (at ETH.MESH 08476340), and submitted to the FDA with the 510(k) for the TVT, was not identical to the TVT device that was launched and sold in the U.S. starting in 1998.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 28. Defendants admit that the mesh used in the IVS and TVT was identical.

REQUEST NO. 29: Admit that the mesh used to treat patients in the IVS device that was used in the Medscand Multicenter Scandinavian Study, signed by Margareta Eriksson on October 17, 1997 (at ETH.MESH 08476340), and submitted to the FDA with the 510(k) for the TVT, was not identical to the TVT mesh in the TVT device that was launched and sold in the U.S. in starting in 1998.

RESPONSE:

Deny.

REQUEST NO. 30: Admit that the IVS device used in the study published with Nilsson, Ulmsten and others as authors entitled, Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary, *International, Urogynecology Journal*, Vol. 12: (2001), was not identical to the TVT device marketed and sold in the U.S. starting in 1998.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 30. Defendants admit that the mesh used in the IVS and TVT was identical.

REQUEST NO. 31: Admit that the IVS device used in the study published with Nilsson, Ulmsten and others as authors entitled, Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary, *International, Urogynecology Journal*, Vol. 12: (2001), was not identical to the TVT device marketed and sold in the U.S. starting in 1998.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 31. Defendants admit that the mesh used in the IVS and TVT was identical.

REQUEST NO. 32: Admit that you paid Medscand Medical AB $400,000.00 or more for submitting to J&J International Clinical Trials that were "acceptable" to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB at ETH.MESH.09746948.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 32. Defendants admit that, pursuant to the License and Supply Agreement dated February 13, 1997, Johnson & Johnson International paid $400,000 to Medscand Medical AB upon the completion of Clinical Trials, as required in Exhibit C to the License and Supply Agreement dated February 13, 1997, specifically the trial known as the Scandinavian Multicenter Trial.

REQUEST NO. 33: Admit that Professor Ulmsten was an investigator in the clinical trial and ultimately an author of the published paper resulting from the clinical trial that resulted in your payment of $400,000.00 to Medscand Medical AB for an "acceptable" Clinical Trial pursuant to Section 3.6 of the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB at ETH.MESH.0974694.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 33. Defendants admit that pursuant to the License and Supply Agreement dated February 13, 1997, Johnson & Johnson International paid $400,000 to Medscand Medical AB upon the completion of Clinical Trials as required in Exhibit C to the License and Supply Agreement dated February 13, 1997, known as the Scandinavian Multicenter Trial, and that Professor Ulf Ulmsten was one of several

investigators in the Scandinavian Multicenter Trial, and one of the authors of the 1998 published paper from that Trial.

REQUEST NO. 34: Admit that Professor Nilsson was an investigator in the clinical trial and ultimately an author of the published paper resulting from the clinical trial that resulted in your payment of $400,000 or more to Medscand Medical AB for an "acceptable" Clinical Trial pursuant to Section 3.6 of the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 34. Defendants admit that pursuant to the License and Supply Agreement dated February 13, 1997, Johnson & Johnson International paid $400,000 to Medscand Medical AB upon the completion of Clinical Trials as required in Exhibit C to the License and Supply Agreement dated February 13, 1997, known as the Scandinavian Multicenter Trial, and that Professor Nilsson was one of several investigators in the Scandinavian Multicenter Trial, and one of the authors of the 1998 published paper from that Trial.

REQUEST NO. 35: Admit that you paid Professor Ulmsten over $2 million as a paid consultant during the years 1997 to 2004.

RESPONSE:

Admit.

REQUEST NO. 36: Admit that you paid Professor Ulmsten over $3 million as a paid consultant during the years 1997 to 2004.

RESPONSE:

Deny.

REQUEST NO. 37: Admit that you paid Professor Ulmsten over $5 million as a paid consultant during the years 1997 to 2004.

RESPONSE:

Deny.

REQUEST NO. 38: Admit that you have paid Professor Nilsson over $1 million as a paid consultant.

RESPONSE:

Deny.

REQUEST NO. 39: Admit that you have paid Dr. Mickey Karram over $1 million as a paid consultant.

RESPONSE:

Admit.

REQUEST NO. 40: Admit that you have paid Dr. Mickey Karram over $2 million as a paid consultant.

RESPONSE:

Deny.

REQUEST NO. 41: Admit that you have paid Dr. Paul Henniford over $1 million as a paid consultant.

RESPONSE:

Defendants interpret Plaintiffs' request to relate to Dr. B. Todd Heniford, not "Dr. Paul Henniford." Subject to this interpretation, Defendants deny Request No. 41.

REQUEST NO. 42: Admit that you have paid Dr. Paul Henniford over $2 million as a paid consultant.

RESPONSE:

Defendants interpret Plaintiffs' request to relate to Dr. B. Todd Heniford, not "Dr. Paul Henniford." Subject to this interpretation, Defendants deny Request No. 42.

REQUEST NO. 43: Admit that you knew that Professor Ulmsten was a shareholder of Medscand Medical AB at the time you paid Medscand Medical AB $400,000.00 or more for submitting to J&J International Clinical Trials that were "acceptable" to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 43. Defendants admit that Johnson & Johnson International and Ethicon knew, at the time that Johnson & Johnson International paid $400,000 to Medscand Medical AB, pursuant to the License and Supply Agreement dated February 13, 1997, that Professor Ulf Ulmsten was a shareholder of Medscand.

REQUEST NO. 44: Admit that you have knowledge that Professor Ulmsten received over $5 million as a shareholder of Medscand Medical AB when J&J purchased the assets of TVT pursuant to the Asset Purchase Agreement between Medscand Medical AB and J&J International dated November 15, 1999.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 44. Defendants have been unable to identify or locate a company witness with personal knowledge of this issue, and Defendants have

not been able to identify or locate any documents that address this issue. Professor Ulmsten is deceased.

REQUEST NO. 45: Admit that you knew that Professor Ulmsten was a shareholder of Medscand Medical AB when J&J purchased the assets of TVT pursuant to the Asset Purchase Agreement dated November 15, 1999.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 45. Defendants admit that Johnson & Johnson International and Ethicon knew, at the time of the Asset Purchase Agreement dated November 15, 1999, that Professor Ulf Ulmsten was a shareholder in Medscand Medical AB. Johnson & Johnson was not a party to the Asset Purchase Agreement.

REQUEST NO. 46: Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten was your paid consultant.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 46. Defendants admit that, at present, they have not identified any TVT marketing materials that expressly state that Professor Ulmsten was a paid consultant.

REQUEST NO. 47: Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Nilsson or any of his studies, the fact that Professor Nilsson was your paid consultant.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 47. Defendants admit that, at present, they have not identified any TVT marketing materials that expressly state that Professor Nilsson was a paid consultant.

REQUEST NO. 48: Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Rezapour or any studies in which he was involved, the fact that Professor Rezapour was your paid consultant.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 48. Defendants admit that, at present, they have not identified any TVT marketing materials that expressly state that Professor Rezapour was a paid consultant.

REQUEST NO. 49: Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Christian Falconer or any studies in which he was involved, the fact that Professor Christian Falconer was your paid consultant.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 49. At present, Defendants have not identified any TVT marketing materials that expressly state that Professor Falconer was a paid consultant.

REQUEST NO. 50: Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten had a conflict of interest due to his relationship with you.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 50. Defendants admit that they have not expressly stated in any TVT marketing materials that there was any "conflict of interest" due to Professor Ulmsten's relationship with Ethicon or Johnson & Johnson.

REQUEST NO. 51: Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Nilsson or any of his studies, the fact that Professor Nilsson has a conflict of interest due to his relationship with you.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 51. Defendants admit that they have not expressly stated in any TVT marketing materials that there was any "conflict of interest" due to Professor Nilsson's relationship with Ethicon or Johnson & Johnson.

REQUEST NO. 52: Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Rezapour or any studies in which he was involved, the fact that Professor Rezapour has a conflict of interest due to his relationship with you.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 52. Defendants admit that they have not expressly stated in any TVT marketing materials that there was any

"conflict of interest" due to Professor Rezapour's relationship with Ethicon or Johnson & Johnson.

REQUEST NO. 53: Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Falconer or any studies in which he was involved, the fact that Professor Falconer has a conflict of interest due to his relationship with you.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 53. Defendants admit that they have not expressly stated in any TVT marketing materials that there was any "conflict of interest" due to Professor Falconer's relationship with Ethicon or Johnson & Johnson.

REQUEST NO. 54: Admit that in 2009 you instituted a policy that prohibits the funding of studies performed by investigators who have a direct ownership interest in the product being studied titled Johnson & Johnson Worldwide MD&D Policy for Investigator-Initiated Studies (Clinical) attached hereto as ETH.MESH.05347755.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 54. Defendants admit that the referenced policy (entitled Johnson & Johnson Worldwide MD&D Policy for Investigator-Initiated Studies (Clinical)) provides that a Johnson & Johnson Medical Device & Diagnostics (MD&D) company may support an investigator-initiated study (IIS) wherein the investigator will have a potential ownership interest in intellectual property (e.g. patent rights or rights to royalty payments) that may arise from the research, but that once an individual has an ownership interest in a MD&D company product, that individual will not be considered for

future support of IIS's in which the safety or effectiveness of that product is under investigation, and further, that restriction is not applicable to IIS's where the use of the product is incidental to the research goals of the IIS. Defendants admit that effective November 14, 2009, for new IIS requests, Ethicon was to comply with this Policy.

REQUEST NO. 55: Admit that your payment to Medscand Medical AB of $400,000.00 for submitting to J&J International Clinical Trials that were "acceptable" to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB, would have violated your current policy entitled Johnson & Johnson Worldwide MD&D Policy for Investigator-Initiated Studies, attached hereto, if such policy was in effect at the time of the payment.

RESPONSE:

Deny.

REQUEST NO. 56: Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson et al., (2001), Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence, Int. *Urogynecol J.* 12 [Suppl]:5-8

RESPONSE:

Deny.

REQUEST NO. 57: Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Falconer C, Rezapour M., 7-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence, *Obstet Gynecol* 104:1259-1262.

RESPONSE:

Deny.

REQUEST NO. 58: Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Palva K, Rezapur M, Falconer C., Eleven Years' Prospective Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Stress Urinary Incontinence, *Int Urogynecol J* (2008) 19:1043-1047.

RESPONSE:

Deny.

REQUEST NO. 59: Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C., Seventeen Years' Follow-up of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence. (2013) *Int Urogynecol J* DOI 10.1007/s00192-013-2090-2, attached hereto.

RESPONSE:

Deny.

REQUEST NO. 60: Admit that you stated to physicians in your marketing material (see, e.g. ETH.MESH 00658058 attached hereto) that the TVT mesh has "large pores".

RESPONSE:

Admit.

REQUEST NO. 61: Admit that no testing was performed by you, or on your behalf, to measure or otherwise determine the pore size of the mesh used in the TVT prior to the creation of this multi-district litigation.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 61. Defendants admit that Ethicon measures TVT mesh via courses and wales, an industry standard in textile construction. "Pore size" has not been defined by medical device industry standards. Defendants further admit that percentage porosity has been defined and measured according to test method OP601-015.

REQUEST NO. 62: Admit that no testing was performed by you, or on your behalf, to measure or otherwise determine the elasticity of the Prolene* mesh used in the TVT devices prior to the creation of this multi-district litigation.

RESPONSE:

Deny.

REQUEST NO. 63: Admit that no testing in humans was performed by you or on your behalf that proves or otherwise supports the claim in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body."

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 63. Defendants admit that no testing was performed in humans with the primary endpoint being whether "the bi-directional elastic property allows adaptation to various stresses encountered in the body." However, Ethicon performed multiple mechanical studies and animal studies and had years of data available which confirmed the safety and efficacy of PROLENE* mesh implants used in the human body, and which confirmed the bi-directional elastic properties of the mesh, as well as its adaptation to various stresses in the body.

REQUEST NO. 64: Admit that the testing you rely on to support your statement in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body" was not testing performed in women with the TVT device.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 64. Defendants admit that no testing was performed in women with the TVT device with the primary endpoint being whether "the bi-directional elastic property allows adaptation to various stresses encountered in the body." However, Ethicon performed multiple mechanical studies and animal studies and had years of data available which confirmed the safety and efficacy of PROLENE* mesh implants used in the human body, and which confirmed the bi-directional elastic property, as well as its adaptation to various stresses in the body.

REQUEST NO. 65: Admit that you never tested the TVT device in live women to determine whether your statement in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body" is a true statement with respect to the TVT mesh when implanted in women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 65. Defendants admit that no testing was performed in women with the TVT device with the primary endpoint being whether "the bi-directional elastic property allows adaptation to various stresses encountered in the body." However, Ethicon performed multiple mechanical studies and animal studies and had years of data available which confirmed the safety and efficacy of PROLENE* mesh implants used in the human body, and which confirmed the bi-directional elastic properties of the mesh, as well as its adaptation to various stresses in the body.

REQUEST NO. 66: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could "rope" and, therefore, become permanently narrowed in width during or after placement by physicians.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 66. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" but clinically significant roping or curling should not occur when the instructions for use (IFU) is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping.

REQUEST NO. 67: Admit that you knew about "roping" of the TVT mesh as stated in ETH.MESH. 01809078, attached hereto, at the time the TVT was first marketed and sold in the U.S.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 67. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping.

REQUEST NO. 68: Admit that you knew about "roping" of the TVT mesh as stated in ETH.MESH. 01809078, attached hereto, by the end of 2004.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 68. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" and received reports of same by the end of 2004, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping.

REQUEST NO. 69: Admit that you knew as of May of 2005 that the TVT mesh could rope or, in other words, stretch to the point of being a "string" when used by physicians as reflected in ETH.MESH 00526473 attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 69. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" and that there was at least one unconfirmed report of TVT mesh stretching as of May 2005, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping.

REQUEST NO. 70: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that reduction in the TVT mesh width due to roping or deconstruction of knit could lead to erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 70. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" and could lead to erosion, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping, and Ethicon warned of erosion in the IFU.

REQUEST NO. 71: Admit that you knew by the end of 2006 that reduction in the TVT mesh width due to roping or deconstruction of knit could lead to erosion as indicated in ETH.MESH .01218019, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 71. Defendants admit that Ethicon considered the possibility that a mesh sling used to treat incontinence could "rope" and could lead to erosion, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant roping, and Ethicon warned of erosion in the IFU.

REQUEST NO. 72: Admit that TVT mesh can curl and/or rope during or after placement by a physician, leading to increased pressure in a localized point on the urethra and potentially causing retention as described in ETH.MESH 01822361, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 72. Defendants admit that Ethicon considered the possibility that roping or curling of TVT mesh could occur, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping and curling, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such occurrences. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 73: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could curl and/or rope during or after placement by a physician, which could then cause or contribute to cause retention as described in ETH.MESH 01822361, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 73. Defendants admit that before marketing TVT, Ethicon considered the possibility that roping or curling of the TVT mesh could occur, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping and curling, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such occurrences. Further, TVT employs a sheath to prevent

the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 74: Admit that you knew as of October of 2006 that the TVT mesh could curl and rope during or after placement by a physician, leading to increased pressure in a localized point on the urethra and potentially causing retention. (*See* ETH.MESH 01822361 attached hereto).

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 74. Defendants admit that Ethicon considered the possibility that roping or curling of the TVT mesh could occur, but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping and curling, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such occurrences. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 75: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the TVT mesh placement resulted in too much localized pressure on the urethra, the TVT mesh could cause an erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 75. Defendants admit that Ethicon was aware that if the surgeon implanting the TVT does not comply with the procedural steps of the IFU for implantation, this mechanism could cause erosion.

REQUEST NO. 76: Admit that you knew as of October of 2006 that if the TVT mesh placement resulted in too much localized pressure on the urethra, the TVT mesh could cause an erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 76. Defendants admit that Ethicon was aware that if the surgeon implanting the TVT does not comply with the procedural steps for implantation in the IFU, this mechanism could cause erosion.

REQUEST NO. 77: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh might not lay flat under the urethra due to roping and curling.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 77. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence may not lay flat under the urethra and could "rope" or "curl," but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping and curling, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, allow the mesh to lie flat and prevent such occurrences. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 78: Admit that you knew as of October of 2006 that the TVT mesh might not lay flat under the urethra due to roping and curling as described in ETH.MESH 01822361 attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 78. Defendants admit that Ethicon was aware of the possibility that a mesh sling used to treat incontinence might not lay flat under the urethra and could "rope" or "curl," but clinically significant roping or curling should not occur when the IFU is appropriately followed. To prevent clinically significant roping and curling, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, allow the mesh to lie flat and prevent such occurrences. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 79: Admit that the TVT IFU has never stated to physicians that the TVT mesh may not lay flat under the urethra due to roping or curling.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 79. Defendants admit that the actual words "the TVT mesh may not lay flat under the urethra due to roping or curling" are not stated in the IFU, as clinically significant roping or curling should not occur when the IFU is appropriately followed. Ethicon's procedural steps for implantation provide instructions that, if properly followed, allow the mesh to lie flat, and instruct how to prevent clinically significant roping and curling. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 80: Admit that the TVT IFU has never stated to physicians that if the TVT mesh does not lay flat under the urethra, the TVT mesh may cause or contribute to cause urinary retention.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 80. Defendants admit that the actual words "if the TVT mesh does not lay flat under the urethra, the TVT mesh may cause or contribute to cause urinary retention" are not stated in the IFU, as clinically significant roping or curling should not occur when the IFU is appropriately followed. Ethicon's procedural steps provide instructions for implantation that, if properly followed, allow the mesh to lie flat, and instruct how to prevent clinically significant roping and curling. Further, TVT employs a sheath to prevent the mesh from clinically significant roping and curling, and Ethicon warned of urinary tract obstruction in the IFU.

REQUEST NO. 81: Admit that the TVT IFU has never stated to physicians that the TVT mesh can rope or curl or narrow in width during or after placement in a women's body.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 81. Defendants admit that the actual words "TVT mesh can rope or curl or narrow in width during or after placement in a women's body" are not stated in the IFU, as clinically significant roping or curling should not occur when the IFU is appropriately followed. Ethicon's procedural steps provide instructions for implantation that, if properly followed, allow the mesh to lie flat, and instruct how to prevent clinically significant roping, curling, and narrowing. Further, TVT employs a sheath to prevent clinically significant roping, curling, and narrowing.

REQUEST NO. 82: Admit that the IFU has never stated to physicians that roping or curling or narrowing of the TVT mesh can cause or contribute to cause erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 82. Defendants admit that the actual words "roping or curling or narrowing of the TVT mesh can cause or contribute to cause erosion" are not stated in the IFU, as clinically significant roping or curling should not occur when the IFU is appropriately followed. Ethicon's procedural steps provide instructions for implantation that, if properly followed, allow the mesh to lie flat, and instruct how to prevent clinically significant roping, curling, and narrowing. Further, TVT employs a sheath to prevent clinically significant roping, curling, and narrowing, and Ethicon warned of erosion in the IFU.

REQUEST NO. 83: Admit that the TVT patient brochures have never informed or advised patients that the TVT mesh could rope, curl, or narrow in width and, as a result, could cause erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 83. Defendants admit that the TVT patient brochures have never contained the actual words "the TVT mesh could rope, curl, or narrow in width and, as a result, could cause erosion," as clinically significant roping or curling or narrowing should not occur when the IFU is appropriately followed. The brochures have, however, warned of the risk of erosion. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures[2] present risks[3]."

[2] Some versions utilize the word "medical."
[3] Some versions include the word "some."

- The ADVERSE REACTIONS section of the brochures warns of "extrusion" and "erosion."

- "There is also a risk of the mesh material becoming exposed into the vaginal canal.[4] Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

- "pain with intercourse, pelvic pain, … wound healing problems … and nerve damage."

- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 84: Admit that the TVT patient brochures have never informed or advised patients that the TVT mesh could rope, curl, or narrow in width and, as a result, could cause urinary retention.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 84. Defendants admit that the TVT patient brochures have never contained the actual words "the TVT mesh could rope, curl, or narrow in width and, as a result, could cause urinary retention," as clinically significant roping or curling or narrowing should not occur when the IFU is appropriately followed. The brochures have, however, warned of the risk of urinary difficulties. More specifically, different brochures over the years have contained the following warnings:

- "All surgical[5] procedures present risks.[6]"

[4] A different version warns that "There is a risk of the mesh material becoming exposed into the vagina."
[5] Some versions utilize the word "medical."
[6] Some versions include the word "some."

- "Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems."

- "Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury."

- Warning of "development of urinary incontinence or voiding difficulties… or difficulty urinating."

- "Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent[7] urinary tract obstruction."

- "Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately" and that "As with other incontinence procedures, de novo detrusor instability may occur."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 85: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh collapsed, erosion could occur.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 85. Defendants admit that prior to marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could collapse and lead to erosion. To maintain the appropriate pore size, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, Ethicon warned of erosion in the IFU.

REQUEST NO. 86: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh were reduced in size during or after placement, erosion could occur.

[7] Some versions include the word "lower."

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 86. Defendants admit that prior to marketing TVT, Ethicon considered the possibility that if the pores of a mesh sling used to treat incontinence significantly reduced in size, erosion could occur. To maintain the appropriate pore size, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, Ethicon warned of erosion in the IFU.

REQUEST NO. 87: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh were reduced in size during or after placement, the risk of [sic] could be increased.

RESPONSE:

Defendants object to Request No. 87 because it is incomplete – namely, it appears that a word is missing. Defendants are unable to admit or deny Request No. 87 as it is unintelligible, in that the Request does not describe what risk could be increased.

REQUEST NO. 88: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could become encapsulated, not incorporated, due to a reduction in the pore size, which could lead to erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 88. Defendants admit that prior to marketing TVT, Ethicon considered the possibility that if the pores of a mesh sling used to treat incontinence were encapsulated, erosion could occur. To maintain appropriate tissue integration, Ethicon selected an appropriate mesh and provided specific procedural steps

for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, Ethicon warned of erosion in the IFU.

REQUEST NO. 89: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could become encapsulated, not incorporated, due to a reduction in the pore size, which could increase the risk of erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 89. Defendants admit that prior to marketing TVT, Ethicon considered the possibility that if the pores of a mesh sling used to treat incontinence were encapsulated, erosion could occur. To prevent clinically significant encapsulation, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, Ethicon warned of erosion in the IFU.

REQUEST NO. 90: Admit that you knew by the end of 2006 that the TVT mesh could become encapsulated, not incorporated, caused by a reduction in the pore size and lead to erosion as indicated in ETH.MESH .01218019, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 90. Defendants admit that by the end of 2006, Ethicon had considered the possibility that if the pores of a mesh sling used to treat incontinence were encapsulated, erosion could occur. To prevent clinically significant encapsulation, Ethicon selected an appropriate mesh and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence, and Ethicon warned of erosion in the IFU.

REQUEST NO. 91: Admit that the TVT IFU has never stated to physicians that a reduction in the pore size in the TVT mesh could lead to erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 91. Defendants admit that the actual words "reduction in the pore size in the TVT mesh could lead to erosion" are not stated in the IFU, but Ethicon warned of erosion in the IFU.

REQUEST NO. 92: Admit that the TVT IFU has never stated to physicians that a reduction in the pore size in the TVT mesh could increase the risk of erosion.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 92. Defendants admit that the actual words "reduction in the pore size in the TVT mesh could increase the risk of erosion" are not stated in the IFU, but Ethicon warned of erosion in the IFU.

REQUEST NO. 93: Admit that the TVT IFU has never stated to physicians that the TVT mesh could become encapsulated caused by a reduction in pore size and could cause or contribute to cause erosion as a result.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 93. Defendants admit that the actual words "TVT mesh could become encapsulated caused by a reduction in pore size and could cause or contribute to cause erosion as a result" are not stated in the IFU, but Ethicon warned of erosion in the IFU.

REQUEST NO. 94: Admit that you knew at the time the TVT was first marketed and sold in the U.S. that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 94. Defendants admit that Ethicon was aware of the possibility that if a mesh sling used to treat incontinence had rough edges, it could cause pain; therefore, Ethicon selected an appropriate mesh.

REQUEST NO. 95: Admit that you knew by the end of 2006 that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 95. Defendants admit that Ethicon was aware of the possibility that if a mesh sling used to treat incontinence had rough edges, it could cause pain; therefore, Ethicon selected an appropriate mesh.

REQUEST NO. 96: Admit that you knew as of January of 2000 that TVT mesh could fray and become narrower in places as a result.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 96. Defendants admit that Ethicon was aware of the possibility the TVT mesh might fray microscopically with no clinically significant consequences to the patient.

REQUEST NO. 97: Admit that you knew as of January of 2000 that TVT mesh could fray and particles of the mesh could break off and remain inside a woman as a result.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 97. Defendants admit that as of January 2000, Ethicon was aware of the possibility the TVT mesh might fray microscopically and, if so, that microscopic particles possibly could break off with no clinically significant consequences to the patient.

REQUEST NO. 98: Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall as described in ETH.MESH 02620914, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 98. Defendants admit that as of May 1999, Ethicon received unconfirmed reports and was aware of the possibility that mesh fibers could protrude through the vagina, also sometimes referred to as erosion, exposure or extrusion, and that Ethicon warned of this risk in its IFU.

REQUEST NO. 99: Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall and cause pain or discomfort to a woman.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 99. Defendants admit that as of May 1999, Ethicon received unconfirmed reports and was aware of the possibility that mesh fibers could protrude through the vagina, also sometimes referred to as erosion, exposure or extrusion, and that Ethicon warned of this risk in its IFU. Defendants further admit that Ethicon was aware that a potential symptom of erosion is pain or discomfort.

REQUEST NO. 100: Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall and cause pain or discomfort to a woman's sexual partner.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 100. Defendants admit that as of May 1999, Ethicon received unconfirmed reports and was aware of the

possibility that mesh fibers could protrude through the vagina, also sometimes referred to as erosion, exposure or extrusion, and that Ethicon warned of this risk in its IFU. Defendants further admit that Ethicon was aware that erosion could present the possibility of pain or discomfort to a woman's sexual partner.

REQUEST NO. 101: Admit that you knew that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto, by the end of 2006.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 101. Defendants admit that by the end of 2006 Ethicon was aware of the possibility that if a mesh sling used to treat incontinence had rough edges, it could cause pain; therefore, Ethicon selected an appropriate mesh.

REQUEST NO. 102: Admit that the TVT IFU has never stated to physicians that the frayed edges or rough edges of the TVT mesh could cause pain to a woman.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 102. Defendants admit that the actual words "frayed edges or rough edges of the TVT mesh could cause pain" are not in the IFU, but Ethicon warned of erosion, a symptom of which can be pain.

REQUEST NO. 103: Admit that the TVT IFU has never stated to physicians that the frayed edges or rough edges of the TVT mesh could cause pain to a woman's sexual partner.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 103. Defendants admit that the actual words "frayed edges or rough edges of the TVT mesh could cause pain to a

woman's sexual partner" are not in the IFU, but Ethicon warned of erosion, a symptom of which can be pain.

REQUEST NO. 104: Admit that your patient brochures have never advised or informed women that the rough or frayed edges of the TVT mesh could cause pain following the TVT procedure.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 104. Defendants admit that the TVT patient brochures have never contained the actual words "rough or frayed edges of the TVT mesh could cause pain following the TVT procedure." Defendants further admit that different brochures over the years have contained the following warnings:

- "All surgical procedures[8] present risks[9]."
- "There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."
- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs."
- Patient brochures and the IFUs have warned in the ADVERSE REACTIONS section of "[p]unctures or lacerations of vessels, nerves, bladder or bowel," and "extrusion, erosion, fistula formation and inflammation."
- Patient brochures and the IFUs have also warned in the WARNINGS & PRECAUTIONS section of post-operative "bleeding or infection."

[8] Some versions utilize the word "medical."
[9] Some versions include the word "some."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 105: Admit that you knew by the end of 2007 that an article in the peer reviewed literature reported that one of the primary problems with using the TVT is that the mesh easily deforms when tensioning under the urethra. (*See* ETH.MESH 00294195 attached hereto).

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 105. Defendants admit that in 2007, the International Urogynecology Journal published an article by Pamela A. Moalli et al., entitled "Tensile Properties of Five Commonly Used Mid-urethral Slings Relative to the TVT," which article became publicly available upon publication, and that the article includes language that "one of the primary problems in using the TVT is that as a result of its low stiffness, the mesh easily deforms when tensioning under the urethra."

However, to put that partial quote in context, it is further admitted that the same article states, at ETH.MESH.00294202: "At a glance, the behavior (low stiffness, easy deformability, and permanent elongation) of the Gynecare and AMS slings seems counterintuitive, as one could envision a hard cough or sneeze generating sufficient force to loosen the sling in the immediate or early postoperative period. However, such behavior in theory also lowers the rate of erosions of a sling into the urethra or bladder. In contrast, a high stiffness material may not yield (elongate) with the application of even high loads (a very heavy cough) and consequently would have an increased risk of erosion into the bladder or urethra. A low stiffness material may also make the sling less likely to obstruct the urethra or cause postoperative voiding dysfunction.

Indeed, rates of these postoperative complications after the placement of a TVT mid-urethral sling may be less common than with traditional slings due to their biomechanical behavior."

REQUEST NO. 106: Admit that you knew by the end of 2007 that the Moalli et al. study, published in the *International Urogynecology Journal* in 2007 compared TVT mesh to other types of meshes in a study of elongation of the meshes and found that there was irreversible deformation of the TVT mesh with very little force and that the mesh easily elongates with very little tension.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 106. Defendants admit that in 2007, the International Urogynecology Journal published an article by Pamela A. Moalli et al., entitled "Tensile Properties of Five Commonly Used Mid-urethral Slings Relative to the TVT", which article became publicly available upon publication, and that the article includes language that, when stretched between two clamps in a testing machine utilized in the testing performed by Drs. Moalli et al., "the mesh easily elongates in response to small changes in force" and "although very little force applied, there is irreversible deformation of the TVT."

However, to put that partial quote in to context, it is further admitted that the same article states, at ETH.MESH.00294202: "At a glance, the behavior (low stiffness, easy deformability, and permanent elongation) of the Gynecare and AMS slings seems counterintuitive, as one could envision a hard cough or sneeze generating sufficient force to loosen the sling in the immediate or early postoperative period. However, such behavior in theory also lowers the rate of erosions of a sling into the urethra or bladder. In contrast, a high stiffness material may not yield (elongate) with the application of even high loads (a very heavy cough) and consequently would have an increased risk of erosion into the bladder or urethra. A low stiffness material may also

make the sling less likely to obstruct the urethra or cause postoperative voiding dysfunction. Indeed, rates of these postoperative complications after the placement of a TVT mid-urethral sling may be less common than with traditional slings due to their biomechanical behavior."

REQUEST NO. 107: Admit that you knew at the time the TVT was first marketed in the U.S. that the TVT mesh could become permanently deformed during insertion of the TVT mesh.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 107. Defendants admit that before marketing TVT, Ethicon considered the possibility that a mesh sling used to treat incontinence could become deformed. To prevent clinically significant deformation, Ethicon selected an appropriate mesh, and provided specific procedural steps for implantation in the IFU that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant deformation.

REQUEST NO. 108: Admit that the IFU has never stated to physicians that the TVT mesh can become deformed with tension during placement.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 108. Defendants admit that the actual words "TVT mesh can become deformed with tension during placement" are not stated in the IFU. Ethicon selected an appropriate mesh, and provided specific procedural steps for implantation in the IFU to prevent clinically significant deformation that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant deformation.

REQUEST NO. 109: Admit that you have known since the TVT was first marketed and sold in the U.S. that the scar tissue that develops around the mesh used in the TVT can cause the TVT mesh to contract following implantation in the human body.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 109. Defendants admit that before marketing TVT, Ethicon was aware that microporous meshes could allow scar tissue to develop around the mesh. To prevent the development of clinically significant scar tissue around the mesh, Ethicon selected a macroporous mesh that allows tissue incorporation.

REQUEST NO. 110: Admit that you have known since at least November of 2002 that TVT mesh can contract following implantation in the human body as a result of the formation of scar tissue throughout or around the mesh as stated in ETH.MESH 03917375, attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 110. Defendants admit that as of November 2002, Ethicon was aware that microporous meshes could allow scar tissue to develop around the mesh, and that scar tissue throughout the mesh could cause a contraction. To prevent the development of clinically significant scar tissue around the mesh, Ethicon selected a macroporous mesh that allows tissue incorporation.

REQUEST NO. 111: Admit that mesh contracture (mesh shortening due to scar tissue) is a complication of the TVT mesh that you have known about since the TVT was first marketed or sold in the U.S.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 111. Normal wound healing can result in contracture without clinical significance. Defendants admit that

before marketing, Ethicon was aware that some mesh constructions could lead to higher contracture rates. To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free.

REQUEST NO. 112: Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in 2012.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 112. Defendants admit that the first patient brochure to contain the actual words "contracture (mesh shortening due to scar tissue)" was copy approved in December 2012. That brochure notes, in relevant part for this Request, in the **Complications Associated with Synthetic Mesh** section that "There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue)."

REQUEST NO. 113: Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in 2012 even though you knew about that complication associated with the TVT for many years.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 113. Defendants admit that the first patient brochure to contain the actual words "contracture (mesh shortening due to scar tissue)" was copy approved in December 2012. That brochure notes, in relevant part for this Request, in the **Complications Associated with Synthetic Mesh** section that "There is a

risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue)." Defendants further admit that Ethicon was aware that normal wound healing can result in contracture without clinical significance. To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free.

REQUEST NO. 114: Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in 2012 even though you knew about that complication associated with the TVT mesh for over ten years.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 114. Defendants admit that the first patient brochure to contain the actual words "contracture (mesh shortening due to scar tissue)" was copy approved in December 2012. That brochure notes, in relevant part for this Request, in the **Complications Associated with Synthetic Mesh** section that "There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue)." Defendants further admit that Ethicon was aware that normal wound healing can result in contracture without clinical significance. To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free.

REQUEST NO. 115: Admit that TVT mesh contracture (mesh shortening due to scar tissue) is associated with pelvic pain.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 115. Normal wound healing can result in contracture without clinical significance. Defendants admit that some women may have reported pelvic pain in the presence of contracture.

REQUEST NO. 116: Admit that TVT mesh contracture (mesh shortening due to scar tissue) is associated with pain with intercourse.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 116. Normal wound healing can result in contracture without clinical significance. Defendants admit that some women may have reported pain with intercourse in the presence of contracture.

REQUEST NO. 117: Admit that you disclosed to patients in a 2012 TVT patient brochure that mesh "contracture (mesh shortening due to scar tissue)" can cause pelvic pain or pain with intercourse.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 117. Defendants admit that the patient brochure copy approved in December 2012 notes, in relevant part for this Request, in the **Complications Associated with Synthetic Mesh** section that "There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue). Pelvic pain, or pain with intercourse, may occur and may resolve with time." Contracture does not, however, necessarily cause pain. Additionally, prior to 2012, the brochures warned of pain, events with symptoms that include pain, and pain with intercourse. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures[10] present risks.[11]"

- "There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

- "As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs."

- Patient brochures and the IFUs have warned in the ADVERSE REACTIONS section of "[p]unctures or lacerations of vessels, nerves, bladder or bowel," and "extrusion, erosion, fistula formation and inflammation."

- Patient brochures and the IFUs have also warned in the WARNINGS & PRECAUTIONS section of post-operative "bleeding or infection."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 118: Admit that you have known that TVT mesh can contract due to scar tissue and lead to pelvic pain or pain with intercourse for more than five years.

RESPONSE:

Defendants object to Request No. 118 because the phrase "for more than five years" is vague and ambiguous; namely, it is not clear whether it refers to the duration of Defendants' knowledge or to the length of time the alleged pain persists. Subject to and without waiving this objection, Defendants deny Request No. 118, except as hereinafter expressly admitted. Defendants admit that Ethicon was aware that normal wound healing could result in contracture

[10] Some versions utilize the word "medical."
[11] Some versions include the word "some."

with or without pelvic pain or pain with intercourse. Defendants further admit that some women may have reported pelvic pain or pain with intercourse in the presence of contracture. To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free. Ethicon further warned that over correction could lead to urinary tract obstruction, a symptom of which can be pain.

REQUEST NO. 119: Admit that you have known that TVT mesh can contract due to scar tissue and lead to pelvic pain or pain with intercourse for more than ten years.

RESPONSE:

Defendants object to Request No. 119 because the phrase "for more than ten years" is vague and ambiguous; namely, it is not clear whether it refers to the duration of Defendants' knowledge or to the length of time the alleged pain persists. Subject to and without waiving this objection, Defendants deny Request No. 119, except as hereinafter expressly admitted. Defendants admit that Ethicon was aware that normal wound healing could result in contracture with or without pelvic pain or pain with intercourse. Defendants further admit that some women may have reported pelvic pain or pain with intercourse in the presence of contracture. To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free. Ethicon further warned that over correction could lead to urinary tract obstruction, a symptom of which can be pain.

REQUEST NO. 120: Admit that the TVT IFU has never stated to physicians anything about TVT mesh contraction.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 120. Defendants admit that the TVT IFU has never contained the actual words "TVT mesh contraction." To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free. Ethicon further warned that over correction could lead to urinary tract obstruction, a symptom of which can be pain.

REQUEST NO. 121: Admit that the TVT IFU has never stated to physicians that mesh contraction or mesh shrinkage following implantation of the TVT can cause chronic pain.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request 121. Defendants admit that the TVT IFU has never contained the actual words, "mesh contraction or mesh shrinkage following implantation of the TVT can cause chronic pain." To prevent clinically significant contracture, Ethicon selected a macroporous mesh, and provided procedural instructions for implantation in the IFU and professional education that, if properly followed, leave the mesh tension free. Ethicon further warned that over correction could lead to urinary tract obstruction, a symptom of which can be pain.

REQUEST NO. 122: Admit that the TVT Patient Brochures have never specifically informed or advised patients that mesh contraction (mesh shortening due to scar tissue) can cause chronic pain.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 122. Defendants admit that the TVT Patient Brochures have never contained the actual words "mesh contraction

(mesh shortening due to scar tissue) can cause chronic pain." The patient brochure copy approved in December 2012 notes, in relevant part for this Request, in the **Complications Associated with Synthetic Mesh** section that "There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue). Pelvic pain, or pain with intercourse, may occur and may resolve with time." Contracture does not, however, necessarily cause pain. Additionally, prior to 2012, the brochures warned of pain and events with symptoms that include pain. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures[12] present risks[13]."
- "There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."
- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs."
- Patient brochures and the IFUs have warned in the ADVERSE REACTIONS section of "[p]unctures or lacerations of vessels, nerves, bladder or bowel," and "extrusion, erosion, fistula formation and inflammation."
- Patient brochures and the IFUs have also warned in the WARNINGS & PRECAUTIONS section of post-operative "bleeding or infection."
- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

[12] Some versions utilize the word "medical."
[13] Some versions include the word "some."

REQUEST NO. 123: Admit that you have approved and put in use more than 20 TVT patient brochures from 2000 until 2013.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 123. Defendants admit that Ethicon copy approved approximately 19 English language patient brochures for the TVT Family of Products from 2000 until 2013. Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny the number of copy approved versions of patient brochures that were put in use.

REQUEST NO. 124: Admit that the "product information" attached to the approved and in-use TVT patient brochures identified in the TVT/SUI Patient Brochures Index and Production Bates Range Chart Produced to Plaintiffs in 08/26/13 was not written in lay person language as recommended by the FDA in its Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers issued on April 19, 2001.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 124. The referenced guidance document is not applicable to TVT patient brochures. Additionally, the brochures are intended to be used by a physician with his or her patient as the physician deems appropriate.

REQUEST NO. 125: Admit that the first approved and in-use TVT patient brochure that included disclosure of the following risks associated with the TVT was the patient brochure approved for use on February 7, 2011: nerve damage that mesh could become exposed into the vaginal canal, that mesh exposure can be associated with pain during intercourse for the patient and her partner, risks of developing urinary incontinence or difficulty urinating, and that

exposure may require treatment, such as vaginal medication or removal of the exposed mesh in the operating room.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 125. Defendants admit that the TVT patient brochure Ethicon copy approved in February 2011 warns in part that:

> "All surgical procedures present some risks. Complications associated with sling procedures with synthetic mesh include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, pain with intercourse and bladder or bowel injury. There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

However, Ethicon warned of these risks in brochures prior to 2011. More specifically, different brochures over the years prior to 2011 have contained the following warnings:

- "All surgical procedures[14] present risks[15]."
- The ADVERSE REACTIONS section of the brochures warns of "extrusion" and "erosion."
- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems."
- "Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury."
- Both the patient brochures and the IFUs warn in the ADVERSE REACTIONS section that "[o]ver correction, i.e. too much tension applied to the tape, may cause temporary or permanent[16] urinary tract obstruction."[17]

[14] Some versions utilize the word "medical."
[15] Some versions include the word "some."
[16] Some versions include the word "lower."

- Both the patient brochures and the IFUs warn in the WARNINGS AND PRECAUTIONS section that "[a]s with other incontinence procedures, de novo detrusor instability may occur."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 126: Admit that the first approved and in-use TVT patient brochure that included disclosure of the following risks associated with the TVT was the patient brochure approved for use on December 10, 2012: pelvic pain, hemorrhage or hematoma, urinary tract infection, development of urinary incontinence, wound healing problems, fistula, injury to ureters, pelvic abscess formation, vaginal scarring or mesh contracture, infection, or inflammation.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 126. Defendants admit that the TVT patient brochure Ethicon copy approved in December 2012 warns in part:

> **Risks Common to All Pelvic Surgeries:** Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage (bleeding) or hematoma (collections of blood in the pelvis), injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula (holes between bladder or bowel and the vagina), injury to ureters (tubes bringing urine from kidneys to bladder), pelvic abscess formation and nerve damage.
>
> **Complications Associated with Synthetic Mesh:**
> There is a risk of the mesh material becoming exposed into the vagina. Mesh exposure can be associated with pain during intercourse for you and your partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room.

[17] Some versions warn in the ADVERSE REACTIONS section that "[i]mproper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction."

There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue). Pelvic pain, or pain with intercourse, may occur and may resolve with time. There is a risk of developing urinary incontinence or difficulty urinating. Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your surgeon and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.

However, Ethicon warned of these risks in brochures prior to 2012. More specifically, different brochures over the years prior to 2012 have contained the following warnings:

- "All surgical procedures[18] present risks[19]."
- The ADVERSE REACTIONS section of the brochures warns of "extrusion" and "erosion."
- "Complications associated with sling procedures with synthetic mesh include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, pain with intercourse and bladder or bowel injury. There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."
- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems."
- "Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury."
- "Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent[20] urinary tract obstruction."[21]
- "Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction."

[18] Some versions utilize the word "medical."
[19] Some versions include the word "some."
[20] Some versions include the word "lower."
[21] Some versions warn in the ADVERSE REACTIONS section that "[i]mproper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction."

- Both the patient brochures and the IFUs warn in the WARNINGS AND PRECAUTIONS section that "[a]s with other incontinence procedures, de novo detrusor instability may occur."

- Both the patient brochures and the IFUs warn in the WARNINGS AND PRECAUTIONS section that "bleeding or infection may occur post-operatively."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 127: Admit that you have known that the following risks are associated with the TVT since at least the year 2000: erosion, extrusion, exposure, pelvic pain, pain with intercourse, urinary tract infection, hematoma, hemorrhage, pelvic abscess formation, infection, inflammation, the development of urinary incontinence, damage to bowel, bladder, and nerves, wound healing problems, difficulty urinating, and that exposure of the mesh may require treatment including removal in the operating room.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 127. Defendants admit the conditions listed in Request No. 127 are either risks or symptoms associated with any surgery for stress urinary incontinence including surgery using the TVT, and other pelvic floor surgeries whether or not mesh is used, except for mesh exposure, erosion, or extrusion.

REQUEST NO. 128: Admit that the TVT IFU has never specifically stated that "dyspareunia" is an adverse reaction associated with the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 128. Defendants admit that the TVT IFU has never contained the actual word "dyspareunia." In the ADVERSE REACTIONS section, however, the IFU warns of conditions potentially associated with dyspareunia including foreign body response; extrusion; erosion; fistula formation;

inflammation; punctures or lacerations of vessels, nerves, bladder, urethra, or bowel; infection; and urinary tract obstruction. Further, the IFU has always noted, under the **Important** section, that "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device." The IFU also warns that "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device." Dyspareunia is a potential complication of all pelvic surgeries recognized by pelvic floor surgeons and urogynecologists.

REQUEST NO. 129: Admit that the TVT IFU has never specifically stated that "wound healing problems" is an adverse reaction associated with the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 129. Defendants admit that the TVT IFU has never contained the actual words "wound healing problems." In the ADVERSE REACTIONS section, however, the IFU warns of conditions potentially associated with wound healing problems including a "foreign body response," as well as "extrusion, erosion, fistula formation, and inflammation." Further, the IFU has always noted, under the **Important** section, that "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device." The IFU also warns that "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device." Wound healing problems are not specific to TVT procedures or, indeed to any pelvic surgeries, and are potential complications recognized by all surgeons.

REQUEST NO. 130: Admit that the TVT IFU has never specifically stated that "rejection of the mesh" is an adverse reaction associated with the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 130. Defendants admit that the TVT IFU has never contained the actual words "rejection of the mesh." In the ADVERSE REACTIONS section, however, the IFU warns of conditions potentially associated with rejection including a "foreign body response," as well as "extrusion, erosion, fistula formation, and inflammation." The IFU further warns in the WARNINGS AND PRECAUTIONS section that removal of the mesh could be required. Further, the IFU has always noted, under the **Important** section, that "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device." The IFU also warns that "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device." The potential for rejection is a known complication recognized by surgeons using mesh devices.

REQUEST NO. 131: Admit that some complications associated with the TVT can be permanent and life altering.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 131. Defendants admit that, as is true of all surgical procedures, some complications may not resolve and this may affect a patient's life; however, permanent de novo complications that affect patients' lives are very rare.

REQUEST NO. 132: Admit that the TVT IFU has never stated to physicians that removal of the mesh might be necessary.

RESPONSE:

Deny.

REQUEST NO. 133: Admit that the TVT IFU has never stated to physicians that removal of the mesh might be difficult or impossible.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 133. Defendants admit that the TVT IFU has never contained the actual words "removal of the mesh might be difficult or impossible." The IFU warns physicians in the WARNINGS AND PRECAUTIONS section that removal of the mesh could be required. Further, the IFU states that "a thin fibrous layer of tissue . . . can grow through the interstices of the mesh . . . [and] incorporat[e] the mesh into adjacent tissue." Moreover, the IFU has always noted, under the **Important** section, that "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device." The IFU also warns that "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device." Surgeons performing surgery for stress urinary incontinence using mesh recognize that tissue integration may make removal difficult.

REQUEST NO. 134: Admit that you have known since at least 2000 that placement of the TVT may result in incomplete or no relief from urinary incontinence.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 134. Defendants admit that the TVT neither guarantees that all patients will have success nor claims that it has been designed to correct all cases of urinary incontinence.

REQUEST NO. 135: Admit that the mesh used in the TVT can cause a chronic foreign body reaction.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 135. Defendants admit that any foreign body implanted in humans, including TVT, may cause a foreign body reaction, and that the PROLENE* in TVT is a permanent device which may elicit a foreign body reaction while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery, and the foreign body reaction associated with PROLENE* implantation alone is not clinically significant.

REQUEST NO. 136: Admit that the mesh used in TVT can cause chronic inflammation.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 136. Defendants admit that any foreign body implanted in humans, including TVT, may cause chronic inflammation, and that the PROLENE* in TVT is a permanent device which may elicit a foreign body reaction while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery, and the chronic inflammation associated with PROLENE* implantation alone is not clinically significant.

REQUEST NO. 137: Admit that the TVT IFU has never stated to physicians that the TVT can cause a chronic foreign body reaction.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 137. Defendants admit that the actual words "TVT can cause a chronic foreign body reaction" are not in the IFU. Ethicon identifies the TVT in the IFU as a permanent implant, with fibrous tissue integrating in the mesh, which communicates to physicians there may be a foreign body reaction while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery and the foreign body reaction associated with PROLENE* implantation alone is not clinically significant.

REQUEST NO. 138: Admit that the TVT IFU has never stated to physicians that the mesh used in TVT can cause chronic inflammation.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 138. Defendants admit that the actual words "TVT can cause chronic inflammation" are not in the IFU. Ethicon identifies the TVT in the IFU as a permanent implant, with fibrous tissue integrating in the mesh, which communicates to physicians there may be a foreign body reaction which includes an inflammatory response while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery and the inflammatory response associated with PROLENE* implantation alone is not clinically significant.

REQUEST NO. 139: Admit that the TVT Patient Brochures have never advised or informed patients that the mesh used in TVT can cause a chronic foreign body reaction.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 139. Defendants admit that the TVT Patient Brochures have never contained the actual words "TVT can cause a

chronic foreign body reaction." Defendants further admit that different brochures over the years have contained the following warnings:

- "All surgical procedures[22] present risks[23]."
- "There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."
- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs."
- Patient brochures and the IFUs have warned in the ADVERSE REACTIONS section of "[p]unctures or lacerations of vessels, nerves, bladder or bowel," and "extrusion, erosion, fistula formation and inflammation."
- Patient brochures and the IFUs have also warned in the WARNINGS & PRECAUTIONS section of post-operative "bleeding or infection."
- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

The patient brochures are designed to be used in consultation with a doctor, and surgeons recognize that all devices implanted into the body, including TVT, are associated with a foreign body response.

REQUEST NO. 140: Admit that the TVT Patient Brochures have never advised or informed patients that the mesh used in TVT can cause chronic inflammation.

[22] Some versions utilize the word "medical."
[23] Some versions include the word "some."

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 140. Defendants admit that the TVT Patient Brochures have never contained the actual words "chronic inflammation." The brochures have, however, warned of the risk of inflammation.

REQUEST NO. 141: Admit that the mesh in the TVT can cause severe inflammation in some women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 141. Defendants admit that in very rare circumstances, a patient could have an uncommon increased inflammation rate based upon her own individual wound healing factors.

REQUEST NO. 142: Admit that the mesh in the TVT can cause chronic inflammation in some women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 142. Defendants admit that any foreign body implanted in humans, including TVT, may cause chronic inflammation, and that the PROLENE* in TVT is a permanent device which may elicit a foreign body reaction while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery, and the chronic inflammation associated with PROLENE* implantation alone is not clinically significant.

REQUEST NO. 143: Admit that you have known since the TVT was first marketed and sold in the U.S. that TVT mesh can cause severe and chronic inflammation in some women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 143. Defendants admit that any foreign body implanted in humans, including TVT, may cause chronic inflammation, and that the PROLENE* in TVT is a permanent device which may elicit a foreign body reaction while it remains in the body. However, PROLENE* has been shown to be one of the least reactive materials used in surgery, and the chronic inflammation associated with PROLENE* implantation alone is not clinically significant. Ethicon admits, however, of the possibility that some women may have an idiosyncratic predisposition to an exaggerated chronic inflammatory response.

REQUEST NO. 144: Admit that the IFU has never stated to physicians that the mesh in the TVT can cause severe and chronic inflammation in some women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 144. Defendants admit that the TVT IFU has never contained the actual words "severe and chronic inflammation." The IFU, however, warns in the ADVERSE REACTIONS section of "extrusion, erosion, fistula formation, and inflammation."

REQUEST NO. 145: Admit that a potential complication of the TVT is repeated occurrences of exposure of the mesh into the vagina.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 145. Defendants admit that erosion is a potential complication associated with the use of a TVT device, that Ethicon warns of erosion in the IFU and patient brochure, and that patients could experience more than one exposure.

REQUEST NO. 146: Admit that the TVT Patient Brochures in existence prior to December of 2008 did not advise or inform patients of the risk of pain with intercourse following implantation of the TVT devices.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 146. Defendants admit that the TVT Patient Brochures prior to 2008 did not include the actual words "pain with intercourse." Prior to December 2008, both the patient brochures and the IFUs warned in the ADVERSE REACTIONS section of "extrusion," "erosion," and other potential complications, the symptoms of which could cause pain with intercourse. Further, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 147: Admit that in December of 2008, Ethicon released a Patient Brochure that identified pain with intercourse as a risk of the TVT for the first time.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 147. Defendants admit that the TVT patient brochure Ethicon copy approved in December 2008 warned that:

> Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

Prior to December 2008, however, both the patient brochures and the IFUs warned in the ADVERSE REACTIONS section of "extrusion," "erosion," and other potential complications the symptoms of which could cause pain with intercourse. Further, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 148: Admit that you knew at the time of the introduction of the TVT devices that pain with intercourse was a potential adverse reaction associated with use of the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 148. Defendants admit that pain with intercourse is a potential symptom of adverse reactions identified in the IFU and may be associated with any surgery for stress urinary incontinence.

REQUEST NO. 149: Admit that chronic pain is a potential risk of the TVT procedure.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 149. Defendants admit that chronic pain is a potential symptom of adverse reactions identified in the IFU and may be associated with any surgery for stress urinary incontinence.

REQUEST NO. 150: Admit that the TVT Patient Brochures in use prior to 2011 do not specifically advise or inform patients that there is a risk of mesh exposure requiring mesh removal in the operating room.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 150. Defendants admit that the TVT patient brochures in use prior to 2011 did not contain the actual words "there is a risk of mesh exposure requiring mesh removal in the operating room," but prior to 2011, both the patient brochures and the IFUs warned in the ADVERSE REACTIONS section of "extrusion" and "erosion." An earlier warning also stated: "There is also a risk of the mesh material becoming exposed. Exposure may require treatment." Further, both the patient brochures and the IFUs warn in the WARNINGS AND PRECAUTIONS section that

"PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material." Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 151: Admit that the TVT Patient Brochure in use starting in January of 2011 was the first Patient Brochure to warn of the risk of mesh exposure that may require mesh removal in the operating room.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 151. Defendants admit that prior to February 2011, the TVT patient brochure did not contain the actual words "the risk of mesh exposure . . . may require mesh removal in the operating room." Defendants admit that the TVT patient brochure Ethicon copy approved in February 2011 warned:

> There is also a risk of the mesh material becoming exposed into the vaginal canal.[24] Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room.

Prior to 2011, both the patient brochures and the IFUs warned in the ADVERSE REACTIONS section of "extrusion" and "erosion." An earlier warning also stated: "There is also a risk of the mesh material becoming exposed. Exposure may require treatment." Further, both the patient brochures and the IFUs warn in the WARNINGS AND PRECAUTIONS section that "PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material." Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

[24] A different version warns that "There is a risk of the mesh material becoming exposed into the vagina."

REQUEST NO. 152: Admit that the TVT patient brochures have never advised or informed patients specifically of the risk of the need for recurrent or multiple surgeries to treat mesh erosion or exposure into the vaginal canal.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 152. Defendants admit that the TVT patient brochures have never contained the actual words "the risk of the need for recurrent or multiple surgeries to treat mesh erosion or exposure into the vaginal canal." For years, however, the brochures have warned of the risks of "extrusion" and "erosion." Further, different brochures over the years have contained the following warnings:

- "PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material."
- "There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."
- "There is also a risk of the mesh material becoming exposed. Exposure may require treatment."
- "Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition."
- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 153: Admit that you did not track when the TVT patient brochures were delivered to any individual physician's office.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 153. Defendants admit that Ethicon did not maintain a centralized tracking system or database for this type of information and that no law or regulation requires that Ethicon maintain a centralized tracking system or database. The manner and means of monitoring the supply of patient brochures to surgeons' facilities fell under the purview of the individual sales representative.

REQUEST NO. 154: Admit that you never instructed a physician to remove older versions of the TVT brochures from his or her office.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 154 as stated. Defendants admit that Ethicon did not provide a formal written communication to all customers to remove older patient brochures; however, when Ethicon sales representatives provided new brochures many would have removed old brochures or instructed physicians to use the new brochures.

REQUEST NO. 155: Admit that the TVT IFU has never included a statement warning or informing physicians that patients may need multiple surgeries to treat mesh erosion or exposure into the vaginal canal.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 155. Defendants admit that the TVT IFU has never contained the actual words “patients may need multiple surgeries to treat mesh erosion or exposure into the vaginal canal.” In the ADVERSE REACTIONS section, the IFU warns of a “foreign body response,” as well as “extrusion, erosion, fistula formation, and inflammation.” Further, the IFUs warn that “PROLENE mesh in

contaminated areas should be used with the understanding that subsequent infection may require removal of the material."

REQUEST NO. 156: Admit that complications resulting from the TVT procedure can permanently impair a woman's ability to engage in comfortable sexual relations.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 156. Defendants admit that in very rare circumstances adverse reactions as identified in the IFU could continue to persist, and that uncomfortable sexual intercourse is a potential complication of any surgery for stress urinary incontinence or pelvic floor repair.

REQUEST NO. 157: Admit that the TVT Patient Brochures do not advise or inform patients that the risk of pain with intercourse following the TVT implantation procedure can be permanent in some women.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 157. Defendants admit that the TVT Patient Brochures do not contain the actual words "the risk of pain with intercourse following the TVT implantation procedure can be permanent in some women." The brochures warn, however, of the risk of pain with intercourse. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures[25] present risks[26]."
- Both the patient brochures and the IFUs have warned in the ADVERSE REACTIONS section of "extrusion" and "erosion."
- "Complications associated with sling procedures with synthetic mesh include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, pain with intercourse and bladder or bowel injury. There is also a risk of the mesh material

[25] Some versions utilize the word "medical."
[26] Some versions include the word "some."

becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

- "Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 158: Admit that Ethicon has known that pain with intercourse was a potential complication of the TVT procedure at all times while selling and marketing the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 158. Defendants admit that pain with intercourse is a potential result of the adverse reactions identified in the TVT IFU, and that uncomfortable sexual intercourse is a potential complication of any surgery for stress urinary incontinence or pelvic floor repair.

REQUEST NO. 159: Admit that Ethicon has known that chronic pain is a potential complication of the TVT procedure at all times while selling and marketing the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 159. Defendants admit that chronic pain is a potential result of the adverse reactions identified in the TVT IFU, and that chronic pain is a potential complication of any surgery for stress urinary incontinence or pelvic floor repair.

REQUEST NO. 160: Admit that the risk of erosion into the vagina following the TVT implantation procedure is a lifelong risk for patients.

RESPONSE:

Admit.

REQUEST NO. 161: Admit that Ethicon has known that the risk of erosion into the vagina following the TVT implantation procedure is a lifelong risk for patients at all times while selling and marketing the TVT in the U.S.

RESPONSE:

Admit.

REQUEST NO. 162: Admit that the TVT Patient Brochures do not advise or inform patients that the risk of erosions or exposures into the vaginal canal is a lifelong risk.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 162. Defendants admit that the TVT Patient Brochures do not contain the actual words "the risk of erosions or exposures into the vaginal canal is a lifelong risk." The brochures have warned for years, however, of the risk of "extrusion" and "erosion." The brochures also have warned of different symptoms associated with those risks. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures present some risks. Complications associated with sling procedures with synthetic mesh include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, pain with intercourse and bladder or bowel injury. There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

- "Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems."

- "Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury."

- "Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately."

- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

- "Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 163: Admit that the TVT IFU has never stated to physicians that the risk of erosion of the mesh is a lifelong risk for patients.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 163. Defendants admit that the TVT IFU has never contained the actual words "the risk of erosion of the mesh is a lifelong risk for patients," but the IFU has always warned of numerous risks, including erosion.

REQUEST NO. 164: Admit that the TVT IFU has never stated to physicians that TVT mesh is associated with excessive scarring around the mesh, scar plate formation, mesh encapsulation, and nerve entrapment.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 164. Defendants admit that the TVT IFU has never contained the actual words "TVT mesh is associated with

excessive scarring around the mesh, scar plate formation, mesh encapsulation, and nerve entrapment." No clinical data shows an association between TVT and excessive scarring, scar plate formation, mesh encapsulation, or nerve entrapment.

REQUEST NO. 165: Admit that it would be untrue for you to state to physicians that the mesh in the TVT does not degrade in a woman's body.

RESPONSE:

Deny.

REQUEST NO. 166: Admit that no testing was performed by J&J and Ethicon, or on its behalf, to measure or otherwise determine the potential for degradation of the TVT mesh prior to the filing of this civil action.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 166. Assuming that "degradation" is defined as "loss of molecular weight and/or tensile strength," the potential for degradation of PROLENE* has been tested by Ethicon.

REQUEST NO. 167: Admit that no testing was performed by you prior to the filing of this civil action, or on your behalf, to measure or otherwise determine the potential for particle loss of the TVT mesh used in the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 167. Numerous implantation studies with mesh look for particle loss, and PSE-02-0579 performed in March 2003 specifically evaluated particle loss.

REQUEST NO. 168: Admit that no testing was performed by you prior to the filing of this civil action, or on your behalf, to measure or otherwise determine the safety or potential health consequences of the particle loss that occurs from the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 168. Numerous implantation studies with mesh look for particle loss, and PSE-02-0579 performed in March 2003 evaluated particle loss.

REQUEST NO. 169: Admit that the only study that was performed by you to analyze the degradation of its mesh was the 10-year Dog Study, Study No ERF-85219.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 169. Assuming that "degradation" is defined as "loss of molecular weight and/or tensile strength," the potential for degradation of PROLENE* has been repeatedly tested. Defendants admit that the 10-year Dog Study, Study No. ERF 85-219, was a study that tested PROLENE* suture filament, the same material used to manufacture TVT mesh. Additionally, a 2 year rat study was conducted and used to support the PROLENE* suture NDA.

REQUEST NO. 170: Admit that the only study that was performed by you to analyze the degradation of its mesh was the 10-year Dog Study, Study No. ERF 85-21933.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 170. Defendants are unaware of 10-year Dog Study, Study No. ERF 85-21933. Assuming that "degradation" is defined as "loss of molecular weight and/or tensile strength," the potential for degradation of PROLENE* has been repeatedly tested. Defendants further admit that the 10-year Dog Study,

Study No. ERF 85-219, was a study that tested PROLENE* suture filament, the same material used to manufacture TVT mesh. Additionally, a 2 year rat study was conducted and used to support the PROLENE* suture NDA.

REQUEST NO. 171: Admit that the 10-year Dog Study No. ERF 85-219 was stopped after seven years.

RESPONSE:

Admit.

REQUEST NO. 172: Admit that the 10-year Dog Study No. ERF 85-219 did not use the identical mesh used in the TVT products.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 172. Defendants admit that the 10-year Dog Study, Study No. ERF 85-219, was a study that tested PROLENE* suture filament, the same material used to manufacture TVT mesh.

REQUEST NO. 173: Admit that the 10-year Dog Study No. ERF 85-219 used suture material only.

RESPONSE:

Admit.

REQUEST NO. 174: Admit that the 10-year Dog Study No. ERF 85-219 was comparing four sutures – Prolene, PVDF, Ethilon and Novafil.

RESPONSE:

Admit.

REQUEST NO. 175: Admit that at year seven of the 10-year Dog Study No. ERF 85-219, the Prolene* suture showed that the "degradation was still progressing after seven years".

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 175. Defendants admit that the 10-year Dog Study No. ERF 85-219 states "Degradation in PROLENE is still increasing . . . ." This quote, however, pertains solely to superficial imperfections seen via SEM at 500x on the surface. Assuming that "degradation" is defined as "loss of molecular weight and/or tensile strength," Defendants admit that there was no functional degradation of the PROLENE* fiber as compared to the control.

REQUEST NO. 176: Admit that at year seven of the 10-year Dog Study No. ERF 85-219, the PVDF suture did not show degradation.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 176. Assuming that "degradation" is defined as "loss of molecular weight and/or tensile strength," Defendants admit that there was no functional degradation of the PVDF fiber as compared to the control.

REQUEST NO. 177: Admit that you did not do any further testing of your Prolene* sutures after the 10-year Dog study No. ERF 85-219 was stopped in year seven.

RESPONSE:

Deny.

REQUEST NO. 178: Admit that you knew prior to the launch of your TVT products that the terms "high responder" and "low responder" referred to the fact that some women would have better post-surgical results than other women after implantation of the TVT products.

RESPONSE:

Defendants object to Request No. 178 as vague and ambiguous because the terms "high responder" and "low responder" are not defined. As a result, Defendants can neither admit nor deny Request No. 178.

REQUEST NO. 179: Admit that you have never performed studies regarding which women would have severe and life-altering complications as a result of implantation of the TVT products.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 179. Ethicon has supported numerous studies, has conducted post marketing surveillance, and continues to review literature, all of which assessed different patient factors to determine the safety and efficacy of TVT. More than 80 randomized controlled trials have assessed the TVT Device and approximately 1,000 studies have addressed the mesh itself. Defendants further admit that it is the most studied SUI device ever sold and that more data is available for the TVT procedure than for any other SUI treatment. Defendants further admit that the clinical data for TVT, some of which includes studies following patients for 10 years, 11.5 years, and 17 years, all demonstrate the safety and efficacy of the TVT device.

REQUEST NO. 180: Admit that you never warned or advised doctors in the TVT IFU that some women could have severe, life-altering complications as a result of implantation of the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 180. Defendants admit that the TVT IFU has never contained the actual words "some women could have severe,

life-altering complications as a result of implantation of the TVT." Defendants further admit that the IFU warns of numerous potential risks that in very rare circumstances could result in severe, life-altering complications. More than 80 randomized controlled trials have assessed the TVT Device and approximately 1,000 studies have addressed the mesh itself. Defendants further admit that it is the most studied SUI device ever sold and that more data is available for the TVT procedure than for any other SUI treatment. Defendants further admit that the clinical data for TVT, some of which includes studies following patients for 10 years, 11.5 years, and 17 years, all demonstrate the safety and efficacy of the TVT device.

REQUEST NO. 181: Admit that you never included in the TVT IFU a statement warning or informing physicians that you had not studied or determined which women might have severe, life-altering complications as a result of implantation of the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 181. Defendants admit that the TVT IFU has never contained the actual words that Ethicon "had not studied or determined which women might have severe, life-altering complications as a result of implantation of the TVT." More than 80 randomized controlled trials have assessed the TVT Device and approximately 1,000 studies have addressed the mesh itself. Defendants further admit that it is the most studied SUI device ever sold and that more data is available for the TVT procedure than for any other SUI treatment. Defendants further admit that the clinical data for TVT, some of which includes studies following patients for 10 years, 11.5 years, and 17 years, all demonstrate the safety and efficacy of the TVT device.

REQUEST NO. 182: Admit that you never warned or notified women in your TVT patient brochures that some women could have severe, life-altering complications as a result of implantation of the TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 182. Defendants admit that the TVT patient brochures have never contained the actual words "some women could have severe, life-altering complications as a result of implantation of the TVT." More than 80 randomized controlled trials have assessed the TVT Device and approximately 1,000 studies have addressed the mesh itself. Defendants further admit that it is the most studied SUI device ever sold and that more data is available for the TVT procedure than for any other SUI treatment. Defendants further admit that the clinical data for TVT, some of which includes studies following patients for 10 years, 11.5 years, and 17 years, all demonstrate the safety and efficacy of the TVT device. Further, the brochures have always warned of potential risks associated with the TVT device. More specifically, different brochures over the years have contained the following warnings:

- "All surgical procedures[27] present risks[28]."
- The ADVERSE REACTIONS section of the brochures warns of "extrusion, erosion, fistula formation, and inflammation."
- "Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair."
- Post-operative "bleeding or infection."
- "Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately."

[27] Some versions utilize the word "medical."
[28] Some versions include the word "some."

- "Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems."

- "Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury."

- "There is also a risk of the mesh material becoming exposed into the vaginal canal.[29] Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room."

- "pain with intercourse, pelvic pain, … wound healing problems … and nerve damage."

- "Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction."

- "Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent[30] urinary tract obstruction."

- "As with all procedures of its type, there's a risk of injury to the bladder and surrounding organs."

- "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment."

- "Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition."

- Lastly, the brochures have always directed women to discuss the risks and benefits with their doctor.

REQUEST NO. 183: Admit that you had knowledge of the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto, since at least the end of 2005.

[29] A different version warns that "There is a risk of the mesh material becoming exposed into the vagina."
[30] Some versions include the word "lower."

RESPONSE:

Admit.

REQUEST NO. 184: Admit that you have known since at least 2006 that polypropylene has been studied in laboratory rats by subcutaneous implantation of discs or powder, and that local sarcomas were induced at the implantation site in such study.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 184. Defendants admit that Ethicon has been aware since 2006 of studies where polypropylene has been studied in laboratory rats by subcutaneous implantation of discs or powder and that some studies have reported "local sarcomas" at the implantation site. Defendants further admit that other studies on this issue report that "it is doubtful whether the tumor like lesions observed in the rat model are really malignant," and no human study has reported an association between polypropylene and local sarcomas at the implantation site.

REQUEST NO. 185: Admit that you have never informed or warned doctors in your TVT IFU that polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder and that local sarcomas were induced at the implantation site in the test, as stated in the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 185. Defendants admit that the TVT IFU has never contained the actual words "polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder and that local sarcomas were induced at the implantation site in the test." Defendants further admit that there is no clinical

data showing an association between TVT and sarcomas, and no human study has reported an association between polypropylene and local sarcomas at the implantation site.

REQUEST NO. 186: Admit that you have never informed doctors or patients about the results of the laboratory rat study that showed cancer at the implantation site of the polypropylene discs or powder, as stated in the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 186. Defendants admit that they did not inform doctors or patients about the rat study cited in the Sunoco Material Safety Data Sheet. Defendants deny that there is any clinical data showing an association between TVT and sarcomas, and no human study has reported an association between polypropylene and cancer at the implantation site.

REQUEST NO. 187: Admit that you have never done any study or testing in humans or animals to determine if polypropylene or polypropylene mesh is associated with or capable of causing cancer.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 187. Ethicon has tested PROLENE* fiber, in the form of sutures, in rats to determine if it is capable of causing cancer. The PROLENE* fiber is the same fiber used to construct the mesh used in the TVT family of products.

REQUEST NO. 188: Admit that by the year 2000 you were aware of the findings of the International Agency for Research on Cancer (IARC 1999) that polypropylene is possibly carcinogenic to humans.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 188. Defendants admit that by the year 2000 Ethicon was aware of the findings of the International Agency for Research on Cancer (IARC 1999) that polymeric implants, like polypropylene, prepared as thin smooth films, are possibly carcinogenic to humans. However, organic polymeric materials, such as polypropylene in the form of sutures or mesh as a group, are not classifiable as to their carcinogenicity to humans.

REQUEST NO. 189: Admit that from 1994-1998, Ethicon collaborated with Professors Klinge and Klosterhalfen in the development of Vypro.

RESPONSE:

Admit.

REQUEST NO. 190: Admit that in approximately 1998, Ethicon learned through its collaboration with Professors Klinge and Klosterhalfen during the development of Vypro, that heavyweight meshes with pore sizes of less than 1 mm in diameter in all directions increase the inflammatory and foreign body response compared to lighter weight meshes with pore sizes greater than 1 mm in diameter in all directions.

RESPONSE:

Defendants object to Request No. 190 because the phrases “heavyweight meshes,” “pore sizes of less than 1 mm in diameter in all directions,” “lighter weight meshes,” and “pore sizes greater than 1 mm in diameter in all directions” are vague and ambiguous because there is no medical device industry standard to measure or define “heavyweight mesh,” “lightweight mesh,” or pore sizes. Subject to and without waiving this objection, Defendants deny Request No. 190.

REQUEST NO. 191: Admit that in approximately 1998, Ethicon learned through its collaboration with Professions Klinge and Klosterhalfen that small-pore mesh can become incorporated entirely in scar tissue, which bridges the whole pore diameter of less than 1 mm in diameter in all directions in scar tissue and can lead to the formation of a rigid scar plate and mesh encapsulation in scar tissue.

RESPONSE:

Defendants object to Request No. 191 because the phrases "small-pore mesh," and "whole pore diameter of less than 1 mm in diameter in all directions" are vague and ambiguous, and because there is no medical device industry standard to measure or define pore sizes. Subject to and without waiving this objection, Defendants deny Request No. 191.

REQUEST NO. 192: Admit that the body's reaction to heavyweight meshes with pore sizes less than 1 mm in diameter in all directions can result in inflammation and scar contraction around the mesh.

RESPONSE:

Defendants object to Request No. 192 because the phrases "heavyweight meshes" and "pore sizes less than 1 mm in diameter in all directions" are vague and ambiguous and because there is no medical device industry standard to measure or define "heavyweight mesh" or pore size. Subject to and without waiving these objections, Defendants deny Request No. 192, except as hereinafter expressly admitted. Defendants admit that the implantation of any mesh may or may not result in inflammation and scar contraction around the mesh in any given person.

REQUEST NO. 193: Admit that inflammatory reaction to heavyweight mesh can form a scar-plate around the mesh prosthetic that results in a firm and contracted mesh.

RESPONSE:

Defendants object to Request No. 193 because the phrases "heavyweight mesh" and "scar-plate" are vague and ambiguous, and because there is no medical device industry standard to measure or define "heavyweight mesh" nor is there a medical definition of "scar-plate." Subject to and without waiving these objections, Defendants deny Request No. 193, except as hereinafter expressly admitted. Defendants admit that inflammatory reaction to any mesh may or may not form a scar around the mesh prosthetic that results in a firm and contracted mesh in any given person.

REQUEST NO. 194: Admit that reducing the amount of foreign body material of heavyweight meshes can reduce the inflammatory response.

RESPONSE:

Defendants object to Request No. 194 because the phrase "heavyweight mesh" is vague and ambiguous, and because there is no medical device industry standard to measure or define "heavyweight mesh." Subject to and without waiving these objections, Defendants deny Request No. 194, except as hereinafter expressly admitted. Defendants admit that reducing the amount of foreign body material of any mesh may or may not reduce an inflammatory reaction in any given person.

REQUEST NO. 195: Admit that increasing the mesh pore size to greater than 1 mm in diameter in all directions can reduce the inflammatory response.

RESPONSE:

Defendants object to Request No. 195 because the phrase "pore size greater than 1 mm in diameter in all directions" is vague and ambiguous, and because there is no medical device industry standard to measure or define pore sizes. Subject to and without waiving such

objections, Defendants deny Request No. 195, except as hereinafter expressly admitted. Defendants admit that increasing pore size may or may not reduce an inflammatory response in any given person.

REQUEST NO. 196: Admit that one of the reasons why you developed lighter weight, larger pore meshes in hernia and pelvic organ prolapse repair was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavy weight, small pore meshes (meshes with a pore size of less than 1 mm in diameter in all directions).

RESPONSE:

Defendants object to Request No. 196 because the phrases "lighter weight, larger pore meshes," "heavyweight, small pore meshes," and "pore size of less than 1 mm in diameter in all directions" are vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore meshes," "heavyweight, small pore meshes," or pore sizes. Subject to and without waiving these objections, Defendants deny Request No. 196, except as hereinafter expressly admitted. Defendants admit that Ethicon has developed a variety of meshes for hernia or pelvic organ repair. Each mesh has a different application and design, and one of the goals to consider in the design of any mesh is the potential for reduction of inflammation and foreign body response, while at the same time ensuring that sufficient mesh exists to accomplish the purpose for which the mesh is designed. Ethicon further admits that it developed appropriate meshes for the appropriate applications.

REQUEST NO. 197: Admit that one of the reasons why you began manufacturing hernia and pelvic organ prolapse repair meshes using Prolene* fibers thinner than the 6 mil Prolene*

fibers used in TVT was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavyweight, small pore meshes.

RESPONSE:

Defendants object to Request No. 197 because the phrase "heavyweight, small pore meshes" is vague and ambiguous, and because there is no medical device industry standard to measure or define "heavyweight, small pore meshes" or pore sizes. Subject to and without waiving these objections, Defendants deny Request No. 197.

REQUEST NO. 198: Admit that one of the reasons why you developed meshes with larger pores than the TVT mesh to be used in hernia repairs and pelvic organ prolapse repairs was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavyweight, small pore meshes.

RESPONSE:

Defendants object to Request No. 198 because the phrases "meshes with larger pores" and "heavyweight, small pore meshes," are vague and ambiguous, and because there is no medical device industry standard to measure or define "heavyweight, small pore meshes" or pore sizes. Subject to and without waiving these objections, Defendants deny Request No. 198, except as hereinafter expressly admitted. Defendants admit that Ethicon has developed a variety of meshes for hernia or pelvic organ repair. Each mesh has a different application and design, and one of the goals to consider in the design of any mesh is the potential for reduction of inflammation and foreign body response, while at the same time ensuring that sufficient mesh exists to accomplish the purpose for which the mesh is designed. Ethicon further admits that it developed appropriate meshes for the appropriate applications.

REQUEST NO. 199: Admit that your Ultrapro mesh used for hernia repair is a lightweight, large pore mesh as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto.

RESPONSE:

Defendants object to Request No. 199 because the phrase "lightweight, large pore mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and neither for the treatment of stress urinary incontinence, because there is no medical device industry standard to measure or define "lightweight, large pore mesh" or pore sizes, and because the study does not include "Ultrapro." Subject to and without waiving these objections, Defendants deny Request No. 199, except as hereinafter expressly admitted. Defendants admit that Ultrapro is lighter in weight than Vypro.

REQUEST NO. 200: Admit that Gynemesh PS is a medium weight mesh, as defined by Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7), with larger pores than the Prolene* mesh used in TVT.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 200. Defendants admit that Gynemesh PS is referred to as medium weight mesh in the referenced articles, evaluating the appropriate mesh for use on hernia repair, but deny that there is any medical device industry standard defining "medium weight mesh."

REQUEST NO. 201: Admit that you have known since the development of Vyprohat lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on

the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of inflammation.

RESPONSE:

Defendants object to Request No. 201 because "Vyprohat" appears to by a typographical error, because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 201, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of inflammation for an individual patient, depending in part upon the surgical application.

REQUEST NO. 202: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size of the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of foreign body response.

RESPONSE:

Defendants object to Request No. 202 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 202, except as hereinafter expressly admitted. Defendants admit that meshes

have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of foreign body response for an individual patient, depending in part upon the surgical application.

REQUEST NO. 203: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of fibrotic bridging.

RESPONSE:

Defendants object to Request No. 203 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh, nor is there a medical definition of "fibrotic bridging." Subject to and without waiving these objections, Defendants deny Request No. 203, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of fibrosis for an individual patient, depending in part upon the surgical application.

REQUEST NO. 204: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of scar plate formation.

RESPONSE:

Defendants object to Request No. 204 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 204, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of scar formation for an individual patient, depending in part upon the surgical application.

REQUEST NO. 205: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh encapsulation in the scar.

RESPONSE:

Ethicon objects to Request No. 205 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 205, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given

implant may or may not decrease the risk of mesh encapsulation for an individual patient, depending in part upon the surgical application.

REQUEST NO. 206: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh contraction or shrinkage.

RESPONSE:

Defendants deny Request No. 206 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 206, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of mesh contraction or shrinkage for an individual patient, depending in part upon the surgical application.

REQUEST NO. 207: Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of patient complications.

RESPONSE:

Defendants object to Request No. 207 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no

medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 207, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of patient complications for an individual patient, depending in part upon the surgical application.

REQUEST NO. 208: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of nerve entrapment.

RESPONSE:

Defendants object to Request No. 208 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 208, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of nerve entrapment for an individual patient, depending in part upon the surgical application.

REQUEST NO. 209: Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on

the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of chronic pain.

RESPONSE:

Defendants object to Request No. 209 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 209, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of chronic pain for an individual patient, depending in part upon the surgical application.

REQUEST NO. 210: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by, can decrease patients' risk of chronic pelvic pain.

RESPONSE:

Request No. 210 is unintelligible and appears to be an error. Accordingly, Defendants can neither admit nor deny this Request.

REQUEST NO. 211: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of erosion.

RESPONSE:

Defendants object to Request No. 211 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 211, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of erosion for an individual patient, depending in part upon the surgical application.

REQUEST NO. 212: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of recurrence.

RESPONSE:

Defendants object to Request No. 212 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 212, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given

implant may or may not decrease the risk of recurrence for an individual patient, depending in part upon the surgical application.

REQUEST NO. 213: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of pelvic organ dysfunction (the loss of pelvic organ function).

RESPONSE:

Defendants object to Request No. 213 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 213, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of pelvic organ dysfunction (the loss of pelvic organ function) for an individual patient, depending in part upon the surgical application.

REQUEST NO. 214: Admit that you have known since the development of Vipro (sic) that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of dyspareunia.

RESPONSE:

Defendants object to Request No. 214 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 214, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of dyspareunia for an individual patient, depending in part upon the surgical application.

REQUEST NO. 215: Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh-related infections.

RESPONSE:

Defendants object to Request No. 215 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 215, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given

implant may or may not decrease the risk of mesh-related infections for an individual patient, depending in part upon the surgical application.

REQUEST NO. 216: Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of additional surgeries necessary to revise and/or remove the mesh.

RESPONSE:

Defendants object to Request No. 216 because the article's failure to properly define a "lighter weight, larger pore" mesh renders it vague and ambiguous, and because there is no medical device industry standard to measure or define "lighter weight, larger pore" mesh or pore sizes. Defendants further object to this Request because it does not identify or define a particular mesh or indication for that mesh. Subject to and without waiving these objections, Defendants deny Request No. 216, except as hereinafter expressly admitted. Defendants admit that meshes have different applications and designs and that a reduction in the amount of mesh for any given implant may or may not decrease the risk of additional surgeries necessary to revise and/or remove the mesh for an individual patient, depending in part upon the surgical application.

REQUEST NO. 217: Admit that under the ISO Elusion cytoxicity [sic] testing conducted by NAmSA in July of 1997, the final TVT device tested positive for severe cytotoxicity.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 217. Defendants admit that the ISO Elusion cytotoxicity testing conducted by NAmSA in July of 1997 showed an

initial positive finding of cytotoxicity *in vitro*, but the finding was not later confirmed via *in vivo* testing. The test referenced in this request is not a final *in vivo* result.

REQUEST NO. 218: Admit that in the CE Mark Technical File (ETH.MESH.06851860) Ethicon acknowledged that the Prolene* mesh used in the TVT device has cytotoxic potential.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 218. Defendants admit in the CE Mark Technical File, Ethicon acknowledged, based upon the unconfirmed ISO Elusion cytotoxicity testing, that PROLENE* mesh used in the TVT device has cytotoxic potential, but Defendants deny that cytotoxicity has been demonstrated *in vivo*.

REQUEST NO. 219: Admit that the TVT IFU has never stated to physicians that the TVT device tested positive by NAmSA for severe cytotoxicity in July of 1997.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 219. Defendants admit that the TVT IFU has never contained the actual words "the TVT device tested positive by NAmSA for severe cytotoxicity in July of 1997." Defendants further admit that the ISO Elusion cytotoxicity testing conducted by NAmSA in July of 1997 showed an initial positive finding of cytotoxicity *in vitro*, but the finding was not later confirmed via *in vivo* testing. The test referenced in this request is not a final *in vivo* result.

REQUEST NO. 220: Admit that the TVT IFU has never stated to physicians that the TVT device has cytotoxic potential.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 220. Defendants admit that the TVT IFU has never contained the actual words "the TVT device has cytotoxic

potential." Defendants further admit that the ISO Elusion cytotoxicity testing conducted by NAmSA in July of 1997 showed an initial positive finding of cytotoxicity *in vitro*, but the finding was not later confirmed via *in vivo* testing.

REQUEST NO. 221: Admit that the original device used by Medscand's Scandinavian Multicenter Study submitted with the 510(k) was different from the finished TVT device which tested severely cytotoxic by NAmSA in 1997 under the ISO Elusion test.

RESPONSE:

Deny.

Respectfully Submitted,

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